



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,235	03/06/2002	Eilaz Babaev	501056.20504 (24372.10)	8665

7590

02/11/2004

William H. Dippert
Cowan, Liebowitz & Latman, P.C.
1133 Avenue of the Americas
New York, NY 10036

EXAMINER

JAWORSKI, FRANCIS J

ART UNIT

PAPER NUMBER

3737

DATE MAILED: 02/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,235

Applicant(s)

BABAEV, EILAZ

Examiner

Jaworski Francis J.

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 - 28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 - 28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 - 2, 6-9, 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, absent an indication of structural interconnection between the power source and the (powered) ultrasound transducer, it becomes unclear what structural combination applicant is claiming. For example an examining table may be powered; similarly the room lighting or the portable recorder or palm pilot onto which a physician is recording may be fairly said to be powered parts of a system under which therapeutic ultrasound is applied. Moreover, it is not clear that the power source has anything to do with the focusing function (meaning the claim 7-type content) as opposed to the power source necessarily present for **any** therapeutic energy delivery device. . Additionally, the language "can be adjusted" is only inferential of any adjustability adaptation of the transducer. For example the direction of a fixed curvature may be altered by a re-positioning in a new direction an entire examination assemblage –patient table and treatment assemblage and/or verification imager. Accordingly the artisan would be wholly uncertain of the scope of this claim..

With respect to claim 2, the language "of a focal point " (as opposed to – at a focal point --) is vague insofar as under one interpretation it is met by the transducer

Art Unit: 3737

acting as a point source emitter (therefore the emitted energy is 'of a focal point' in type) regardless of how the curvature acts to focus.

Claim 6 improperly depends from itself. For the sake of examination on the merits, this claim is presumed to depend from claim 1.

With respect to claim 7, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 7 recites the broad recitation separately, and the claim also recites individually which is the narrower statement of the range/limitation. (The term 'separately' is generic to 'separately from each other' as well as 'separately from the emission or sensing power source' or 'along separate power busses' i.e. 'separate in what sense?' whereas 'individually' is specific to the former term.)

Art Unit: 3737

With respect to claim 8, it is unclear whether applicant is attempting to claim that the transducers are adapted to be powered meaning of powered type (i.e. active vs passive transducers) or that they are driven by a power source which is unclaimed.

With respect to claim 9, insofar as applicant is merely claiming a desirable result of en-bloc movement, it is unclear whether the structure modification is merely that all transducers vibrate ultrasonically in unison, or focal motion occurs in unison or the overall device is such that it may be moved from place to place.

With respect to claim 11, the language "must be moved... instant" is unclear since motional changes are decidedly not instant because of inertia and frailty of parts whereas non-motional electronic time-delay focusing is essentially instantaneous because it avoids such inertia/frailty and is limited to the small time ranges fixed by ultrasound tissue propagation speeds.

With respect to claims 12 – 18, it is unclear whether applicant is referring to cycling of the mechanical movement of focusing or to characteristics of modulation of the ultrasound carrier or to variations of the carrier itself, since no generator structure is being defined and claimed.

With respect to claim 14, there is lack of antecedent basis for "the ultrasound frequency". (Note that only claim 12 establishes that a single frequency drives the transducer, and that claim 13 escapes such a rejection since a modulated frequency may be single or plural as in phase shift vs frequency modulation.)

Art Unit: 3737

[Parenthesized claim numbers associated with sentences of the rejection identify the specific claim or claims being addressed by the sentences.]

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-11 are rejected under 35 U.S.C. 102(b) as anticipated by Schafer (US5193527). In Schafer, a powered ultrasound generator 1 is taught. Schafer is anticipatory under the principle of inherency wrt '102 since while a literal showing of a power source is absent no interpretation of its disclosure is possible that does not involve powering of the energy-delivering transducer. (Claim 1). Fig. 5A, 5B and 6A, 6B show respective mechanisms under which sections curvature sections 5 and 6 may towards each other or or pivot apart to move section focus points 9, 10 out of overlap thereby changing the focal point or effective focal point (Claims 2, 3). Four segments numbered as 5-8 in Figure 3c are preferably used. (Claim 6). Col. 4 lines 49-52 teaches that the individual such segments may be individually moved. Since no indication is made that the claim 1 'power source' is automatic or electrical or associated with transducer segment movement, the aforementioned teaching of individual segment motion inherently invokes a motive force to effect the motion, analogous to the claim 1 argument supra. (Claim 7). Individual energy delivery segments are by definition powered delivery elements, again extending the claim 1 anticipatory reasoning (Claim 8). Recalling the '112 2d argument re claims 1, 9 supra, claim 9 may be interpreted to

Art Unit: 3737

simply refer to an overall movable device; moreover the instruction to 'move together' col. 2 line 33 is tantamount to 'move in unison' in the vernacular. (Claim 9). Central portion 4 (cross-section Fig. 1d and Fig. 2b) functionally exists while the transducer segments are all apart (Fig. 4b, 5a). Such an orifice, apparently blind-ending on the base on which the transducers are slid and/or pivoted, is a structural adaptation capable of holding a small camera or transducer. (Claim 10). Since the invention is practiced for rapid lesion destruction to minimize overall energy delivery (col. 1 lines 37-42), the aforementioned claim 9 unison movement is effectively a teaching of rapid focal change. (Claim 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer as applied to claim 1 above, and further in view of Law et al (US5762066). It would have been obvious in view of the latter col. 14 lines 42 – 58 and col. 15 lines 3-58 to form a rigid and non-elastic containment for a focused diathermy transducer in order to avoid pinching tissue in the transducer's proximity and in order to accurately direct the ultrasound energy without alterations in critical angle back-reflections caused by varying couplant membrane deflection with application pressure against the body surface.

Claims 5, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer as applied to claim 1 above, and further in view of Hassler (US4957099). Since Schafer teaches that a focused ultrasound therapy transducer may be adapted to undergo curvature change and for diathermy or lithotripsy application (col. 1 lines 14-20), it would have been obvious in view of Hassler to incorporate an array of adjustable transducers 1 within a flexible-elastic enclosure i.e. bellows 4 and its flexible coupling membrane in order to acoustically couple the energy to the patient's body. (Claim 5). It would also have been obvious in view of Hassler elements 11 and 17 as exemplary to adjust the curvature of the overall radiation surface for a transducer-lens set (i.e. for 2, 14 of Schafer or for 1,25 of Hassler) by using a move-in-unison powering via rods 11, 17 in conjunction with powering devices 21, 22 since the focal region often needs to be moved deeper within the body such as f1 to f2 in Hassler. (Claims 8 – 9). Further, it would have been obvious in view of Hassle to centrally position ultrasound probe 26 in a central orifice of the transducer sections 1 since this ensures that the targeting or treatment progress imaging is confocal with the lesion and the delivered energy focus.(Claim 10).

Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer as applied to claims 1, 6 above, and further in view of Dory (US5150711). Dory includes teaching that focused ultrasound diathermy wavetrains at a pre-selected fixed emission frequency selected according to lesion depth were prior art thereto, see col. 1 lines 27-41. It would therefore have been obvious to use a fixed pre-selected frequency in Schafer for the reason that the lesion is at a fixed depth, the focal depth of the

Art Unit: 3737

transducer is defined by emission frequency, one wants the focus sharp to minimize collateral damage, and the frequency must so be both fixed and discretely matched to the lesion's depth. (claim 12). This described frequency application is intermittently interrupted for imaging and therefore is amplitude-modulated by having a fractional duty cycle (Claim 13). The improvement of Dory, moreover, see col.6 lines 57 – 68, is to make the treatment rapid e.g. .5 - 3 seconds to further minimize collateral damage by computing a maximum delivery power for such an optimum frequency to gain the desired near instantaneous temperature rise whereupon Schafer might be expected to adopt such an advantageous advancement. (Claims 11 – 12). The treatment wave in Dory is pulsed with a 98% duty cycle to allow for imaging, see col. 4 lines 33-62. That is to say, a constant or fixed frequency wave in Dory is also characterizable as a rectangular-modulated or pulsed wave as the reference effectively states. (Claims 14, 16). Such a pre-selected frequency e.g. the 1 Mhz is understood to be a sinusoidal excitation of the carrier absent an indication of a non-standard waveshape. (Claim 15). The claiming of further modulation shapes is considered to be a matter of design choice absent a showing of criticality by applicant since tissue ultrasound diathermy is effectively a focal power delivery/heating process enactable under any modulation envelope and duty cycle which delivers sufficient average energy to cause the necrotizing local temperature rise. (Claims 17-18).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer in view of Dory as applied to claim 13 above, and further in view of .Rolt et al (US5501655). It would have been obvious in view of the latter to effect the rapid heat-

Art Unit: 3737

lesioning called for in Dory by using such modulated ultrasound, see cols. 2-3 bridging, where the modulation may include triangular modulation rich in inter-harmonics effective for rapid heating, see col. 6 lines 7-23. .

Claims 1 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner (US5143063) in view of Reichenberger (US4664111), further in view of Schafer.

Fellner teaches a method for lipolytic therapy to treat obesity over areas of the body using programmed translational control of ultrasound energy delivery focus, see Fig. 2 and discussion thereof as well as col. 5 lines 3-22. The implementing Fig. 2 device of Fellner is akin to that of the face figure of Reichenberger, which evidences via 13A-13C that this category of chambered ultrasound treatment device is also amenable to staggered or variable focusing exactly like the Schafer device. Therefore:it would have been obvious to adopt the Schafer teaching that the focal point should be staggered to tailor the energy distribution to correlate with the morphology of the treated region, here an area being lipolyzed. It is noted that tumor diathermy is not mutually exclusive of lipolytic therapy since some tumors have a fatty or lipomatous content and lipolysis is essentially tissue necrosis of fatty i.e. adipose tissue.

[Claim 1 is grouped for this rejection to accommodate the consistency of base reference usage if the method be construed as a dependent claim. With respect to remaining dependent claims 20-28, the core claim 19 argument is carried forward with the secondary references applied for features discussed against the corresponding apparatus claim features above.]

Art Unit: 3737

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner in view of Reichenberger and Schafer as applied to claim 19 above, and further in view of Law et al, for reasons paralleling the claim 4 rejection using Law et al supra.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner in view of Reichenberger and Schafer as applied to claim 19 above, and further in view of Hassler, for reasons paralleling the claim 5 rejection using Hassler supra.

Claims 22 – 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner in view of Reichenberger and Schafer as applied to claim 19 above, and further in view of Dory et al, for reasons paralleling the claim 12 –18 rejection using Dory et al supra.

Claim 28 is further rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner in view of Reichenberger and Schafer and Dory et al as applied to claim 23 above, and further in view of Rolt et al, for reasons paralleling the rejection using Rolt et al against claim 18 supra.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

FJJ:fjj

02-05-04

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 - 2, 6-9, 11-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, absent an indication of structural interconnection between the power source and the (powered) ultrasound transducer, it becomes unclear what structural combination applicant is claiming. For example an examining table may be powered; similarly the room lighting or the portable recorder or palm pilot onto which a physician is recording may be fairly said to be powered parts of a system under which therapeutic ultrasound is applied. Moreover, it is not clear that the power source has anything to do with the focusing function (meaning the claim 7-type content) as opposed to the power source necessarily present for **any** therapeutic energy delivery device. . Additionally, the language "can be adjusted" is only inferential of any adjustability adaptation of the transducer. For example the direction of a fixed curvature may be altered by a re-positioning in a new direction an entire examination assemblage –patient table and treatment assemblage and/or verification imager. Accordingly the artisan would be wholly uncertain of the scope of this claim..

With respect to claim 2, the language "of a focal point " (as opposed to – at a focal point --) is vague insofar as under one interpretation it is met by the transducer

Art Unit: 3737

acting as a point source emitter (therefore the emitted energy is 'of a focal point' in type) regardless of how the curvature acts to focus.

Claim 6 improperly depends from itself. For the sake of examination on the merits, this claim is presumed to depend from claim 1.

With respect to claim 7, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 7 recites the broad recitation separately, and the claim also recites individually which is the narrower statement of the range/limitation. (The term 'separately' is generic to 'separately from each other' as well as 'separately from the emission or sensing power source' or 'along separate power busses' i.e. 'separate in what sense?' whereas 'individually' is specific to the former term.)

Art Unit: 3737

With respect to claim 8, it is unclear whether applicant is attempting to claim that the transducers are adapted to be powered meaning of powered type (i.e. active vs passive transducers) or that they are driven by a power source which is unclaimed.

With respect to claim 9, insofar as applicant is merely claiming a desirable result of en-bloc movement, it is unclear whether the structure modification is merely that all transducers vibrate ultrasonically in unison, or focal motion occurs in unison or the overall device is such that it may be moved from place to place.

With respect to claim 11, the language "must be moved...instant" is unclear since motional changes are decidedly not instant because of inertia and frailty of parts whereas non-motional electronic time-delay focusing is essentially instantaneous because it avoids such inertia/frailty and is limited to the small time ranges fixed by ultrasound tissue propagation speeds.

With respect to claims 12 – 18, it is unclear whether applicant is referring to cycling of the mechanical movement of focusing or to characteristics of modulation of the ultrasound carrier or to variations of the carrier itself, since no generator structure is being defined and claimed.

With respect to claim 14, there is lack of antecedent basis for "the ultrasound frequency". (Note that only claim 12 establishes that a single frequency drives the transducer, and that claim 13 escapes such a rejection since a modulated frequency may be single or plural as in phase shift vs frequency modulation.)

[Parenthesized claim numbers associated with sentences of the rejection identify the specific claim or claims being addressed by the sentences.]

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-11 are rejected under 35 U.S.C. 102(b) as anticipated by Schafer (US5193527). In Schafer, a powered ultrasound generator 1 is taught. Schafer is anticipatory under the principle of inherency wrt '102 since while a literal showing of a power source is absent no interpretation of its disclosure is possible that does not involve powering of the energy-delivering transducer. (Claim 1). Fig. 5A, 5B and 6A, 6B show respective mechanisms under which sections curvature sections 5 and 6 may towards each other or or pivot apart to move section focus points 9, 10 out of overlap thereby changing the focal point or effective focal point (Claims 2, 3). Four segments numbered as 5-8 in Figure 3c are preferably used. (Claim 6). Col. 4 lines 49-52 teaches that the individual such segments may be individually moved. Since no indication is made that the claim 1 'power source' is automatic or electrical or associated with transducer segment movement, the aforementioned teaching of individual segment motion inherently invokes a motive force to effect the motion, analogous to the claim 1 argument supra. (Claim 7). Individual energy delivery segments are by definition powered delivery elements, again extending the claim 1 anticipatory reasoning (Claim 8). Recalling the '112 2d argument re claims 1, 9 supra, claim 9 may be interpreted to

Art Unit: 3737

simply refer to an overall movable device; moreover the instruction to 'move together' col. 2 line 33 is tantamount to 'move in unison' in the vernacular. (Claim 9). Central portion 4 (cross-section Fig. 1d and Fig. 2b) functionally exists while the transducer segments are all apart (Fig. 4b, 5a). Such an orifice, apparently blind-ending on the base on which the transducers are slid and/or pivoted, is a structural adaptation capable of holding a small camera or transducer. (Claim 10). Since the invention is practiced for rapid lesion destruction to minimize overall energy delivery (col. 1 lines 37-42), the aforementioned claim 9 unison movement is effectively a teaching of rapid focal change. (Claim 11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer as applied to claim 1 above, and further in view of Law et al (US5762066). It would have been obvious in view of the latter col. 14 lines 42 – 58 and col. 15 lines 3-58 to form a rigid and non-elastic containment for a focused diathermy transducer in order to avoid pinching tissue in the transducer's proximity and in order to accurately direct the ultrasound energy without alterations in critical angle back-reflections caused by varying couplant membrane deflection with application pressure against the body surface.

Claims 5, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer as applied to claim 1 above, and further in view of Hassler (US4957099). Since Schafer teaches that a focused ultrasound therapy transducer may be adapted to undergo curvature change and for diathermy or lithotripsy application (col. 1 lines 14-20), it would have been obvious in view of Hassler to incorporate an array of adjustable transducers 1 within a flexible-elastic enclosure i.e. bellows 4 and its flexible coupling membrane in order to acoustically couple the energy to the patient's body. (Claim 5). It would also have been obvious in view of Hassler elements 11 and 17 as exemplary to adjust the curvature of the overall radiation surface for a transducer-lens set (i.e. for 2, 14 of Schafer or for 1,25 of Hassler) by using a move-in-unison powering via rods 11, 17 in conjunction with powering devices 21, 22 since the focal region often needs to be moved deeper within the body such as f1 to f2 in Hassler. (Claims 8 – 9). Further, it would have been obvious in view of Hassle to centrally position ultrasound probe 26 in a central orifice of the transducer sections 1 since this ensures that the targeting or treatment progress imaging is confocal with the lesion and the delivered energy focus.(Claim 10).

Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer as applied to claims 1, 6 above, and further in view of Dory (US5150711). Dory includes teaching that focused ultrasound diathermy wavetrains at a pre-selected fixed emission frequency selected according to lesion depth were prior art thereto, see col. 1 lines 27-41. It would therefore have been obvious to use a fixed pre-selected frequency in Schafer for the reason that the lesion is at a fixed depth, the focal depth of the

Art Unit: 3737

transducer is defined by emission frequency, one wants the focus sharp to minimize collateral damage, and the frequency must so be both fixed and discretely matched to the lesion's depth. (claim 12). This described frequency application is intermittently interrupted for imaging and therefore is amplitude-modulated by having a fractional duty cycle (Claim 13). The improvement of Dory, moreover, see col.6 lines 57 – 68, is to make the treatment rapid e.g. .5 - 3 seconds to further minimize collateral damage by computing a maximum delivery power for such an optimum frequency to gain the desired near instantaneous temperature rise whereupon Schafer might be expected to adopt such an advantageous advancement. (Claims 11 – 12). The treatment wave in Dory is pulsed with a 98% duty cycle to allow for imaging, see col. 4 lines 33-62. That is to say, a constant or fixed frequency wave in Dory is also characterizable as a rectangular-modulated or pulsed wave as the reference effectively states. (Claims 14, 16). Such a pre-selected frequency e.g. the 1 Mhz is understood to be a sinusoidal excitation of the carrier absent an indication of a non-standard waveshape. (Claim 15). The claiming of further modulation shapes is considered to be a matter of design choice absent a showing of criticality by applicant since tissue ultrasound diathermy is effectively a focal power delivery/heating process enactable under any modulation envelope and duty cycle which delivers sufficient average energy to cause the necrotizing local temperature rise. (Claims 17-18).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schafer in view of Dory as applied to claim 13 above, and further in view of Rolt et al (US5501655). It would have been obvious in view of the latter to effect the rapid heat-

Art Unit: 3737

lesioning called for in Dory by using such modulated ultrasound, see cols. 2-3 bridging, where the modulation may include triangular modulation rich in inter-harmonics effective for rapid heating, see col. 6 lines 7-23. .

Claims 1 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner (US5143063) in view of Reichenberger (US4664111), further in view of Schafer.

Fellner teaches a method for lipolytic therapy to treat obesity over areas of the body using programmed translational control of ultrasound energy delivery focus, see Fig. 2 and discussion thereof as well as col. 5 lines 3-22. The implementing Fig. 2 device of Fellner is akin to that of the face figure of Reichenberger, which evidences via 13A-13C that this category of chambered ultrasound treatment device is also amenable to staggered or variable focusing exactly like the Schafer device. Therefore:it would have been obvious to adopt the Schafer teaching that the focal point should be staggered to tailor the energy distribution to correlate with the morphology of the treated region, here an area being lipolyzed. It is noted that tumor diathermy is not mutually exclusive of lipolytic therapy since some tumors have a fatty or lipomatous content and lipolysis is essentially tissue necrosis of fatty i.e. adipose tissue.

[Claim 1 is grouped for this rejection to accommodate the consistency of base reference usage if the method be construed as a dependent claim. With respect to remaining dependent claims 20-28, the core claim 19 argument is carried forward with the secondary references applied for features discussed against the corresponding apparatus claim features above.]

Art Unit: 3737

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner in view of Reichenberger and Schafer as applied to claim 19 above, and further in view of Law et al, for reasons paralleling the claim 4 rejection using Law et al supra.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner in view of Reichenberger and Schafer as applied to claim 19 above, and further in view of Hassler, for reasons paralleling the claim 5 rejection using Hassler supra.

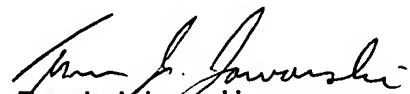
Claims 22 – 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner in view of Reichenberger and Schafer as applied to claim 19 above, and further in view of Dory et al, for reasons paralleling the claim 12 –18 rejection using Dory et al supra.

Claim 28 is further rejected under 35 U.S.C. 103(a) as being unpatentable over Fellner in view of Reichenberger and Schafer and Dory et al as applied to claim 23 above, and further in view of Rolt et al, for reasons paralleling the rejection using Rolt et al against claim 18 supra.

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 703-308-3061.

FJJ:fjj

02-05-04


Francis J. Jaworski
Primary Examiner